



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/814,865

03/30/2004

Fidel Realyvasquez

CSI-2025

5630

7590
Jeffrey J. Hohenshell
710 Medtronic Parkway
Minneapolis, MN 55432

05/14/2008

EXAMINER

NGUYEN, VI X

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

05/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/814,865	Applicant(s) REALYVASQUEZ ET AL.	
	Examiner Victor X. Nguyen	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 8-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/7/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. This application contains claims 8-20 drawn to non-elected inventions. In 02/22/2008, applicant elected to prosecute Species 1 that associated with figures 2a-c. Furthermore, applicant has stated that claims 1-7 read upon the elected species 1 and species 2. To further the prosecution of the application, the examiner has elected claims 1-7, which read on Species 1. Non-elected claims 8-20 are withdrawn from further consideration. The requirement is deemed proper and is therefore made **Final**.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/551,856. They are not patentably distinct from each other because they recite the same subject matters as following: Heart valve leaflet removal apparatus comprising a pair of cutting elements, where one of the cutting elements being rotatably coupled to the other of the pair of cutting elements, a holder coupled to one of the cutting elements and where the cutting elements

and holder being configured for delivery to the aortic valve leaflets through an aortotomy formed in the patient's aorta.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102 (b) as being anticipated by Stevens (US 5,370,685).

Steven disclose endovascular heart procedure having the limitations as recited in the above listed claim, including: a pair of cooperating cutting elements 40, where one of the cutting elements being rotatably coupled to the other of the pair of cutting elements (see col. 6, lines 57-60), where a holder 35 coupled to one of the cutting elements. Regarding the intended use of "a holder coupled to one of the cutting elements and adapted to receive the cut leaflets and the cutting elements and holder being configured for delivery to the aortic valve leaflets through an aortotomy formed in the patient's aorta": The statement of intended use and other functional statements have been carefully considered but are deemed not to impose any structure limitations on the claims distinguishable over Steven reference which is capable of being used as claimed if one desires to do so; and where the pair of cutting elements are radially collapsible (fig. 5), where the cutting elements have radial dimension as best described in fig. 6, where the device further has a sheath at 50.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Regarding claim 5, Stevens discloses the invention substantially as claimed, but Stevens is silent regarding the cutting elements have a memory shape.

It would have been obvious obvious to one having ordinary skill in the art at the time the invention was made to construct the device, including the cutting elements, to have a memory shape, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use or as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Regarding claims 6-7, Stevens discloses the invention substantially. Although, Stevens does not disclose the cutting elements comprising a spiral configuration or the holder comprising a conical configuration.

It would have been to one ordinary skilled in the art at the time the invention was made to construct the cutting element or holder of Stevens' device with a spiral or conical configuration, since applicant has not disclosed that doing so solves any stated problem or is anything more than selecting one of numerous shapes or configurations a person ordinary skill in the art would find available to substitute with a spiral or conical configuration since this again involves nothing

Art Unit: 3773

more than substitution of functionally equivalent a spiral or conical configuration known in the medical art.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No.6,695,859 to Golden

U.S. Pat. No. 5,221,259 to Weldon

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ho Jackie can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victor X Nguyen
Examiner
Art Unit 3734

VN
5/5/2008

/Julian W. Woo/
Primary Examiner, Art Unit 3773